

No. 12-458

In the Supreme Court of the United States

W.L. GORE & ASSOCIATES, INC.,

Petitioner,

v.

C.R. BARD, INC., BARD PERIPHERAL
VASCULAR, INC., AND DAVID GOLDFARB, M.D.,

Respondents.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit**

REPLY BRIEF FOR PETITIONER

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
REPLY BRIEF FOR PETITIONER	1
I. The Federal Circuit’s Novel Joint-Inventorship Rule Is Improper	1
II. The Relevant Facts Only Underscore The Federal Circuit’s Departure From Section 116.....	4
III. The Correct Definition Of Joint Inventorship Remains Exceedingly Important.....	9
CONCLUSION	12

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Ethicon, Inc. v. U.S. Surgical Corp.</i> , 135 F.3d 1456 (Fed. Cir. 1998).....	1
<i>General Electric Co. v. Jewel Incandescent Lamp Co.</i> , 326 U.S. 242 (1945).....	8
<i>PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.</i> , 12 F. Supp. 2d 69 (D. Mass. 1998)	8
<i>Reeder-Simco GMC, Inc. v. Volvo GM Heavy Truck Corp.</i> , 374 F.3d 701 (8th Cir. 2004)	2
<i>Volvo Trucks North America, Inc. v. Reeder-Simco GMC, Inc.</i> , 546 U.S. 164 (2006).....	2
Statutes	
35 U.S.C. § 102(b).....	12
35 U.S.C. § 116	<i>passim</i>
35 U.S.C. § 202(c)(7)	10
35 U.S.C. § 256(b).....	11
35 U.S.C. § 262	11

TABLE OF AUTHORITIES—Cont’d

	Page(s)
35 U.S.C. § 282	11
Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284	10, 11, 12
 Other Authorities	
Armitage, <i>Understanding the America Invents Act and Its Implications for Patenting</i> , 40 AIPLA Q.J. 1 (2012).....	11
Bui, <i>An Overview of Patent Reform Act of 2011</i> , 93 J. PAT. & TRADEMARK OFF. SOC’Y 441 (2011).....	11
Chisum, <i>Priority Among Competing Patent Applicants Under the America Invents Act</i> , available at http://ssrn.com/abstract=1969592	11
Dreyfuss, <i>Collaborative Research: Conflicts on Authorship, Ownership and Accountability</i> , 53 VAND. L. REV. 1161 (2000).....	9, 10
Dzeguze, <i>Avoiding the “Fifth Beetle” Syndrome: Practical Solutions to Minimizing Joint Inventorship Exposure</i> , 6 J. MARSHALL REV. INTELL. PROP. L. 645 (2007).....	10

TABLE OF AUTHORITIES—Cont'd

	Page(s)
PTO Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 43,759 (July 26, 2012).....	12

REPLY BRIEF FOR PETITIONER

The Petition makes three basic arguments. *First*, the Federal Circuit has announced a new rule for joint inventorship, which contravenes statutory text and this Court's guidance. *Second*, that rule was used here to deny co-inventorship to a researcher whose contribution to the final invention was so large that it bordered on sole inventorship. *Third*, the Federal Circuit's rule is important and threatens to impede valuable innovation by discouraging scientific collaboration. The Brief in Opposition has no persuasive answers.

I. The Federal Circuit's Novel Joint-Inventorship Rule Is Improper

The opinion below expressly treats communication of the invention's key requirement as a prerequisite for joint inventorship—twice. The majority “h[e]ld” that the jury could “find that Goldfarb and Cooper were not joint inventors *because* Cooper did not communicate to Goldfarb that the internodal distance was the key to creating successful grafts, and *therefore*, the jury could have reasonably concluded” that Cooper's contribution was insufficient. Pet. App. 14a (emphasis added). It noted that Cooper had not “communicated that key requirement to Goldfarb,” concluding that, “[a]ccordingly, substantial evidence supports the jury's finding.” *Id.* at 18a (emphasis added).

“Inventorship is a question of law.” *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). Therefore, those statements meant more than that the record supported a factual finding. The

absence of a communication of the invention's key requirement was legally dispositive—a rule of law.

Bard does not contest that the rule contradicts 35 U.S.C. § 116. Pet. 18-19. Nor does Bard deny that the rule undermines case law, Pet. 20-21, and erases the distinction between joint- and sole-inventorship standards, Pet. 27-28.

Faced with this unwelcoming terrain, Bard takes the only path available: denying the existence of the novel rule. First, it argues that the majority did nothing more than apply “settled law,” as expressed in an “agreed-upon model [jury] instruction,” to hold that “substantial evidence supported the jury’s finding.” Opp. 1. The fallacy of Bard’s argument is illustrated by *Volvo Trucks North America, Inc. v. Reeder-Simco GMC, Inc.*, 546 U.S. 164 (2006). In *Volvo* a divided court purported to apply settled law to evaluate the sufficiency of the evidence, and Volvo had not challenged the jury instructions. See *Reeder-Simco GMC, Inc. v. Volvo GM Heavy Truck Corp.*, 374 F.3d 701, 707-08, 709-10 (8th Cir. 2004). Yet this Court’s reversal established the most important price-discrimination precedent in decades. A court that *purports* to apply settled law to the evidence can, *by treating particular facts as dispositive*, establish a new legal standard. That is what the Federal Circuit did here.

Next, Bard argues that the passages Gore cites from the opinion below were just a response to “Gore’s *factual* assertion” about the significance of Cooper’s sending the embodiment of the invention to Goldfarb. Opp. 17. The opinion below did respond to that Gore argument—on pages 15a and 16a. But the two general statements of the “key requirement” rule

are on pages 14a and 18a and make no reference to the argument Bard highlights.

Moreover, the Federal Circuit’s interpretation of *Cooper II* (see Pet. App. 15a) reaffirms the breadth of its holding. Addressing sole inventorship, *Cooper II* noted that “Cooper was not required to communicate his *conception*” to Goldfarb—*i.e.*, the “formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice” (Pet. App. 139a)—but then faulted Cooper for his failure to convey “*the importance of fibril length.*” *Id.* at 146a (quoted at 15a) (emphasis added). *Cooper II* thus distinguished between communicating the *conception* (which is the complete invention) and communicating the *key requirement* of fibril length. The former was not necessary for Goldfarb’s work to inure to Cooper’s benefit, but the latter was. Pet. App. 146a. The opinion below has now adopted the latter requirement *also* for joint inventorship. See Pet. App. 18a. Bard has no answer except to confuse the two concepts *Cooper II* distinguished. Opp. 24.

The adoption of a standard from the *inurement* context collapses the concepts of joint and sole inventorship, which are really quite different. Pet. 27-29. Under the majority opinion, Cooper could establish joint inventorship only if he could also prove that Goldfarb’s work inured to his benefit; but that would make Cooper the *sole* inventor. If joint inventorship under 35 U.S.C. § 116 has *any* meaning, however, it must embrace a broader category of contributions than sole inventorship. Bard ignores this argument.

II. The Relevant Facts Only Underscore The Federal Circuit's Departure From Section 116

Bard tries to obscure the Federal Circuit's error with numerous irrelevant facts. In truth, however, a small number of facts, all contemporaneously documented, are dispositive.

A. Legal standards distinguish the *operative* facts from the dross that surrounds them. This case began with many issues, but only one remains. The record is full of facts that have nothing to do with inventorship. Nevertheless, rather than offer any meaningful discussion of the law of inventorship, Bard offers a 38-page recitation of its trial case.

That absence is telling—prior cases *that Goldfarb won but now does not wish to discuss* state the relevant law and its application to these facts. Inventorship requires (i) conception, the “formation” of the “definite” idea of the “complete and operative invention”; and (ii) reduction to practice, here by making an embodiment of the invention and recognizing that it works for its intended purpose. *Cooper I*, Pet. App. 118a. Cooper, without Goldfarb's help, conceived the invention by early June 1973. *Id.* at 119a. Then, in July 1973, Goldfarb conceived the invention and, by recognizing that the Cooper-supplied tubes embodied the invention, completed the reduction to practice that Cooper had begun by making and supplying the invention-embodiment tubes. *Id.* at 128a.

Hence, the only criterion for inventorship—*sole* inventorship—that Goldfarb met but Cooper did not was completing a reduction to practice (*i.e.*, establishing that Cooper's embodiment worked). Had

Cooper communicated his independent conception upon noticing the fibril length, Goldfarb's completion of the reduction to practice would have inured to Cooper's benefit—and Cooper would be the *sole* inventor. *Cooper II*, Pet. App. 146a. None of this is in dispute.

B. These principles clarify the only factual question now relevant: What did Cooper contribute to the invention? The answer: everything significant *except for* communicating to Goldfarb that he should examine fibril length.¹

Before Goldfarb ever heard of Gore-Tex® in February 1973, Cooper had collaborated with doctors in designing, testing, and re-designing tubes (as the correspondence shows) and coauthored a paper explaining that Gore-Tex® “consists of tiny nodules of [PTFE], interconnected by thin fibrils.” C.A. App. A14267. The paper, published in *Surgery* in December 1972, included a photomicrograph showing this microstructure. *Id.* at A14261-69. (Cooper had been studying Gore-Tex® under a microscope. *Id.* at A39602.) This understanding of the microstructure did not originate with Goldfarb. But see Opp. 8.

Cooper and his coauthors specifically focused on the space between nodes. They planned to “determine the micron size of pores in order to compare results between experiments” C.A. App. A14269. “Pore size,” as measured by the bubble test, was one way to describe the open space between the nodes. *Id.* at A40402; see Pet. 6. Bard's insistence

¹ *Cooper II* expressly held that Goldfarb's confirmation of success *did* inure to Cooper's benefit, the implantation having been undertaken “at Cooper's request.” Pet. App. 144a.

that this *micron*-sized property is somehow *macroscopic*, Opp. 5-6, 8-10, 30, makes no sense.

By the time *Surgery* published the paper, Cooper was comparing tubes based on their microstructure—his three-structure experiment. Pet. 5-7. Receiving Sharp’s results in early April 1973, Cooper learned that a certain microstructure was more likely to succeed than others. He sent four newly made tubes embodying this microstructure to Goldfarb—along with Sharp’s synopsis of his successful implantation—in April 1973. Pet. 8.

Thus, far from being “undifferentiated,” Opp. 2, 7, 17, 23, the tubes Cooper sent Goldfarb in April belonged to a new generation. None of Gore’s earlier tubes had benefited from the three-structure experiment. With it, Cooper had confirmed that the space between nodes mattered—and his team at Gore built that knowledge into the tubes he gave to Goldfarb, who used them to confirm success and measured their fibril length.²

Now consider one of Bard’s favorite factual assertions: that Cooper’s needle holes in the April tubes made it harder, not easier, to conclude that inter-nodal distance was key. That is not necessarily so; but, if so, so what? First, the petition notes (at 8)—and Bard does not dispute—that two-thirds of one of the two pairs of tubes supplied to Goldfarb in April were used in the successful experiment. Second and

² Indeed, just weeks after Cooper sent the tubes to Goldfarb, Cooper discovered that fibril length was a better measure of the microstructure that provides a successful graft. Pet. 7. The bubble test was still a useful proxy: *all* of the preserved grafts from the April batch had the proper fibril length. Pet. 11.

more important, all scientific discovery results from pursuing unsuccessful as well as successful leads. If it is true that Cooper pursued an unsuccessful idea, that is at most another reason why he is not the *sole* inventor, but does nothing to suggest that he is not a *joint* inventor.

Return to the legal framework and focus on what is actually claimed. The invention is a vascular prosthesis made of a particular material, not a surgical technique or something else. U.S. Patent 6,436,135, reproduced at C.A. App. A13449-61. Cooper and his Gore team designed and created the prosthesis made of that material, which is an “embodiment of the invention.” *Cooper II*, Pet. App. 143a (“The record establishes that Cooper made an embodiment of the invention . . .”).

The claimed invention is the tubes. Cooper’s contribution to that claimed invention is not diminished by Goldfarb’s testing of the tubes. Unlike Cooper, Goldfarb could implant the material in animals. Unlike Goldfarb, Cooper and his Gore team could vary the microstructure and produce prostheses designed to achieve success. Joint inventorship exists to foster exactly this sort of collaboration. See Pet. 32-33.

In sum, Cooper contributed nearly everything possible to Goldfarb’s recognition of the claimed property of successful tubes—including *the embodiment of the invention* from the latest generation of tubes—short of telling Goldfarb about fibril length. Had he told Goldfarb about fibril length, Cooper would have been the *sole* inventor. If the lower threshold for *joint* inventorship means anything, Cooper is a joint inventor.

With that background, it is easy to see why Bard cannot distinguish *General Electric Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242 (1945), on the ground that, but for Goldfarb, “no one knew how to make an ePTFE graft at all.” Opp. 34 (emphasis omitted). The facts stated by the Federal Circuit itself show otherwise. Cooper’s plant made the graft Goldfarb used. Even the majority below recognized “Cooper’s collaboration with Goldfarb.” Pet. App. 14a. This collaboration figured no less prominently here than it did in *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 12 F. Supp. 2d 69 (D. Mass. 1998). *Contra* Opp. 34. The conflicts in the case law along with the importance of the issue amply justify review.

C. Bard’s mantra that the facts are disputed, Opp. 1-2, 3, 20, 30, 32, rings hollow, for Bard identifies nary a *relevant* fact in dispute. Instead, Bard lards its brief with “facts” that are irrelevant, misleading, or both.

For example, ignoring the law of inventorship, Bard cites its favorite facts from after July 1973, the invention date awarded to Goldfarb. *E.g.*, Opp. 11 (tube specifications), 12 (alleged conversion), 12 (experiments by other surgeons). No facts after that date mattered to the patent; if they did, Goldfarb could not have been awarded a July 1973 invention date.³

³ Despite Bard’s implications (Opp. 7, 11, 13-14, 32-33), Gore does not contest any PTO determination. In particular, the PTO never rejected Cooper’s co-inventorship of any of the asserted claims of the issued patent—whether in the interference, in the Bard-cited 1981 examiner decision on Goldfarb’s application (which did not include those claims), or

This case does not involve the application of settled law to disputed facts. The dispositive facts establishing Cooper's joint inventorship are contemporaneously documented, few in number, and undisputed. Only by adopting its new, far-reaching rule could the Federal Circuit hold otherwise. That grave error deserves correction.

III. The Correct Definition Of Joint Inventorship Remains Exceedingly Important

Despite Bard's contrary arguments (Opp. 35-38), joint inventorship is now more important than ever.

A. The modern trend is toward greater collaboration, with more patents filed jointly every year. Pet. 29-31. That trend was well under way when Congress amended Section 116 in 1984 to "nurtur[e] collaborative efforts and improving information flows." Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership and Accountability*, 53 VAND. L. REV. 1161, 1210 (2000). Congress determined that a proper background standard for joint inventorship is necessary to encourage collaboration.

Yet, according to Bard, joint research agreements and other private arrangements are a complete solution to the joint-inventorship problem. Opp. 35-36. The *amicus* briefs supporting the Petition show otherwise. As DuPont and Milliken explain, "there are entire industries" whose existing practices will be severely disrupted by the Federal Circuit's holding; and Dr. Chakrabarty observes that it "could lead to serious abuse in the academic research community."

elsewhere. An order inviting the views of the Solicitor General (who would consult with the PTO) might be appropriate if this Court is not prepared to grant the Petition outright.

DuPont/Milliken Br. 12; Chakrabarty Br. 15.⁴ Even prestigious and sophisticated researchers sometimes fail to iron out patent ownership problems *ex ante*. Dreyfuss, *supra*, 53 VAND. L. REV. at 1173-74.

As the Petition explained, such difficulties are to be expected in the fundamentally unpredictable context of research and innovation. Pet. 36 n.11. Joint development agreements “will not guard against the unforeseeable breakthrough.” Dzeguze, *Avoiding the “Fifth Beatle” Syndrome: Practical Solutions to Minimizing Joint Inventorship Exposure*, 6 J. MARSHALL REV. INTELL. PROP. L. 645, 666 (2007). The appropriate background rule is crucial—and that is what Congress provided by modifying Section 116.

In addition, although *ownership* of a patent can be assigned, inventorship itself is not assignable. And inventor status can have significant consequences—both reputational and financial. For instance, the Bayh-Dole Act requires universities to share royalty revenues with inventors for inventions arising out of federally sponsored research. 35 U.S.C. § 202(c)(7). Joint inventorship remains important.

B. Changes in statutory law have made joint inventorship more, not less, significant. Bard argues that the Leahy-Smith America Invents Act (“AIA”) makes joint inventorship “unlikely to be litigated as

⁴ It is unsurprising that DuPont and Milliken hedge their bets about whether the Federal Circuit adopted a new requirement. *Amici* are alarmed about this requirement, as the time and effort they put into an *amicus* brief demonstrate. Yet they understandably do not wish to have an *amicus* brief quoted back at them later if this Court denies review.

an invalidity defense going forward.” Opp. 37. The articles Bard cites actually say the opposite. Bui, *An Overview of Patent Reform Act of 2011*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 441, 457 (2011) (“the change will likely have little material impact on patent litigation practices”); Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 12-13 (2012) (making no reference to the availability of joint inventorship as an invalidity defense).⁵

The author of the leading treatise has explained Bard’s error: it “is a bad argument to say that improper inventorship can no longer invalidate a patent,” because the argument “assumes that, by an oblique and ambiguous omission, Congress altered a 200-year[-]old fundamental requirement for obtaining a patent.” Chisum, *Priority Among Competing Patent Applicants Under the America Invents Act*, available at <http://ssrn.com/abstract=1969592>. Post-AIA, the joint-inventorship standard of 35 U.S.C. § 116 remains unchanged, and Section 282 provides an invalidity defense against patents that do not comply with the requirements of Part II of the statute—which includes Section 116. Moreover, 35 U.S.C. § 256(b) states that omitting inventors will not invalidate a patent “if it can be corrected as

⁵ The pages Bard cites note only that a patentee can eliminate an invalidity defense *by using the Section 256 mechanism* to add omitted co-inventors (as has long been the case) but, under the new law, need not prove absence of deceptive intent in the initial omission. That is irrelevant here. Bard has not corrected its omission, and could not do so without precluding the present suit since adding Cooper would give his assignee, Gore, the right to use the patented invention. 35 U.S.C. § 262.

provided in this section,” unmistakably implying that uncorrected errors *would* invalidate a patent. In short, joint inventorship remains an important invalidity defense.

Other AIA features have made joint inventorship *more* significant. Under the pre-AIA regime, patentees were entitled to eliminate, as prior art, any work done in the year before their filing date. 35 U.S.C. § 102(b). Under the AIA, the general rule will be that a patentee cannot eliminate pre-filing work, with a series of exceptions that turn on whether the work came directly or indirectly from the inventor or a “joint inventor.” AIA, Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285-86 (amending Section 102). The new statute thus builds a joint-inventorship inquiry into its fundamental prior-art provisions, making the standards governing that inquiry all the more important. See, *e.g.*, PTO Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 43,759, 43,761-63, 43,765-70 (July 26, 2012).

Joint inventorship, therefore, is more crucial than ever. The decision below throws the law of joint inventorship into confusion. That body of law, which this Court has never directly addressed in the modern era, warrants this Court’s attention. This case is the right vehicle.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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